

**IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF WEST VIRGINIA
AT CLARKSBURG**

ASTRAZENECA AB and ASTRAZENECA
PHARMACEUTICALS LP,

Plaintiffs,

v.

MYLAN PHARMACEUTICALS INC. and
KINDEVA DRUG DELIVERY L.P.,

Defendants.

Civil Action No.: 1:22:cv-00035-GMG

DEFENDANTS' MOTION TO DISMISS

Defendants, Mylan Pharmaceuticals Inc. ("MPI") and Kindeva Drug Delivery L.P. ("Kindeva") (collectively, "Defendants"), respectfully move this Court to dismiss Count 1 of Plaintiffs' Complaint for failure to state a claim under Rule 12(b)(6). The basis for this motion, as is set forth more fully in the memorandum of law being filed contemporaneously with this motion, is that Count 1 seeks relief under the Hatch-Waxman Act, and specifically under the provisions of 35 U.S.C. § 271(e). But, because the '558 patent was not even in existence during the time in which Mylan's ANDA was awaiting FDA approval, the provisions of the Hatch-Waxman act do not apply and no relief can be afforded to Plaintiffs under the Act.

For the foregoing reasons, and those set forth in Defendants' memorandum of law, Defendants respectfully request that the Court dismiss Count 1 and Prayer for Relief paragraphs A and C-F under Rule 12(b)(6) for failure to state a claim.

Respectfully submitted this 1st day of June, 2022.

/s/ Gordon H. Copland

Gordon H. Copland (WVSB #828)

William J. O'Brien (WVSB #10549)

STEPTOE & JOHNSON, PLLC

400 White Oaks Boulevard

Bridgeport, WV 26330

T: (304) 933-8000

gordon.copland@steptoe-johnson.com

william.obrien@steptoe-johnson.com

*Counsel for Defendants Mylan Pharmaceuticals Inc.
and Kindeva Drug Delivery L.P.*

CERTIFICATE OF SERVICE

I hereby certify that on the 1ST day of June, I filed the foregoing “**Defendants’ Motion to Dismiss**” with the Clerk using the Court’s CM/ECF system, which will send notification of the filing to all counsel of record.

/s/ Gordon H. Copland

Gordon H. Copland (WV Bar #828)
gordon.copland@steptoe-johnson.com
STEPTOE & JOHNSON PLLC
400 White Oaks Boulevard
Bridgeport, WV 26330
Phone: (304) 933-8000